



PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/712,546	
			Filing Date	November 12, 2003	
			First Named Inventor	Joseph S. Podolski	
			Group Art Unit	1614	
Examiner Name					
Sheet	1	of	5	Attorney Docket Number	07189.0028.CPUS02

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
2	A1	4,061,733	12/06/1977	Gunjekar	
	A2	5,728,688	03/1998	Labrie	
	A3	5,861,389	01/1999	Radlmaier	
	A4	6,096,338	08/01/2000	Lacy	
	A5	6,126,969	10/03/2000	Shah	
	A6	6,129,933	10/10/2000	Oshlack	
	A7	6,143,353	11/07/2000	Oshlack	
	A8	6,190,591	02/20/2001	Van Lengerich	
	A9	6,221,399	04/24/2001	Rolfes	
	A10	6,248,363 B1	06/19/200-1	Patel	
	A11	6,391,920 B1	05/21/2002	Fisch	
	A12	US 2002/0120012 A1	09/29/2002	Fisch	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁴
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
6	B1	EP 0888775 A2	07/01/1999	Medical College of Hampton Roads		
	B2	WO 03/005954 A2	01/23/2003	Zonagen, Inc.		
	B3	WO 95/35093	12/28/1995	University of Nebraska Board of Regents		
	B4	JP 4-312522	11/04/92	Kawashima		
	B5	WO 01/91744 A1	12/20/2001	Fisch		

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Sheet	2	5	Attorney Docket Number	07189.0028.CPUS02

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T ²
	C1	Ben-Jonathan, N., et al., "Dopamine as a Prolactin (PRL) Inhibitor," Endocr. Rev. 22(6), pp.724-63 (2001)	
	C2	Breznik, R., et al., "Effectiveness of Antiestrogens in Infertile Men," Arch. Androl., Vol. 31(1), pp. 43-48 (1993)	
	C3	Check, J., et al., "Empirical Therapy of the Male with Clomiphene in Couples with Unexplained Infertility" Int. Journal Fertil., Vol. 34(2), pp. 120-122 (1989)	
	C4	Cooper, A., et al., "The Effects of Clomiphene in Impotence A Clinical and Endocrine Study," British Journal of Psychiatry, Vol. 120, pp. 327-330 (1972)	
	C5	Cunningham, G., et al., "Testosterone Replacement Therapy and Sleep-Related Erections in Hypogonadal Men," J. Clin. Endocrinol. Metab., Vol. 70, No. 3, pp. 792-797 (1990)	
	C6	Dangprasit, P., et al., "Development of Diclofenac Sodium Controlled Release Solid Dispersions by Spray Drying Using Optimization Strategy I. Powder Formulation," Drug. Devel. And Industrial Pharm. 21(20), pp.2323-2337 (1995)	
	C7	Davidson, J., et al., "Effects of Androgen on Sexual Behavior in Hypogonadal Men," J. Clin. Endocrinol. Metab., Vol. 48, No. 6, pp. 955-958 (1979)	
	C8	Ernst, S., et al., "Stereochemistry of Geometric Isomers of Clomiphene: A Correction of the Literature and A Reexamination of Structure-Activity Relationships," J. Pharmaceut. Sci., Vol. 65, pp. 148-150 (1976)	

Not considered

Examiner Signature	<i>Bail</i>	Date Considered	2-16-06
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	C9	Feldman, H., et al., "Age Trends in the Level of Serum Testosterone and Other Hormones in Middle-Aged Men: Longitudinal Results from the Massachusetts Male Aging Study," J Clin Endocrinol Metab. 87(2), pp.589-598 (2002)	
	C10	Fuse, H., et al., "Changes in Seminal Plasma Transferring Concentration Following Administration of Clomiphene Citrate," Archives of Andrology, Vol. 31, pp. 139-145 (1993)	
	C11	Guay, A., et al., "Effect of Raising Endogenous Testosterone Levels in Impotent Men with Secondary Hypogonadism: Double Blind Placebo-Controlled Trial with Clomiphene Citrate," Journal of Clinical Endocrinology and Metabolism, Vol. 80, No. 12, pp. 3546-3552 (1995)	
	C12	Guay, A., et al., "Possible Hypothalamic Impotence," Urology, Vol. 38, No. 4, pp. 317-322 (1991)	
	C13	Guay A., et al., "Results of Double Blinded Treatment With Clomiphene Citrate In Patients With Hypogoadotropic Hypogonadism," Annual Meeting of the Endocrine Society, Abstract No. 386, (June 1993)	
	C14	Hirshkowitz, M., et al., "Androgen and Sleep-Related Erections," J. Psychosomatic Research, Vol. 42, No. 6, pp. 541-546 (1997)	
	C15	Homonnai, Z., et al., "Clomiphene Citrate Treatment in Oligozoospermia: Comparison Between Two Regimens of Low-Dose Treatment," Fertility And Sterility, Vol. 60, No. 5, pp. 801-804 (1988)	
	C16	Jarow, J., "Nonsurgical Treatment of Male Infertility: Empiric Therapy," Therapy, Chapter 23, pp. 410-422 (date of Publication Not Available)	

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	C17	Kharenko, A., et al., "Controlled Release From Oral Formulations Based on Interpolymeric Polymethacrylic Acid – Polyethylene Glycol Complex," Proceed. Intern. Symp. Control Rel. Bioact. Mater., Vol. 22, pp. 232-233 (1995)	
	C18	Matsumoto, A., et al., "Human Chorionic Gonadotropin and Testicular Function: Stimulation of Testosterone, Testosterone Precursors, and Sperm Production Despite High Estradiol Levels," Journal of Clinical Endocrinol. And Metab. Vol. 56, No. 4, pp. 720-728 (1983)	
	C19	Merck Index, 13th Ed., Entry 2410, p. 417 (2001)	
	C20	Meshali, M., et al., "Effect of Interpolymer Complex Formation of Chitosan With Pectin or Acacia on the Release Behaviour of Chlorpromazine HCl" Int. J. Phar., Vol. 89, pp. 177-181 (1993)	
	C21	Morales, A., et al., "Andropause: A Misnomer For A True Clinical Entity," J. Urol., Vol. 163, No. 3, pp. 705-12 (March 2000) Abstract	
	C22	Purvis, K., et al., "Stability of Sperm Characteristics in Men with Disturbances in Sperm Quality," Int. Journal Androl., 12, pp. 171-178 (1989)	
	C23	Sodergaard, R., et al., "Calculation of Free and Bound Fractions of Testosterone and Estradiol-17 β to Human Plasma Proteins at Body Temperature," J. Steroid Biochem, Vol. 16, pp. 801-810 (1982)	
	C24	Sternbach, et al., "Age-associated Testosterone Decline in Men: Clinical Issues for Psychiatry," Am. J. Psychiatry, Vol. 155, No. 10, pp. 1310-8 (1998) Abstract	

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	C25	Suzuki, et al., "Endocrine Environment of Benign Prostatic Hyperplasia: Prostate Size and Volume are Correlated with Serum Estrogen Concentration," Scand. J. Urol. Nephrol., Vol. 29, No. 1, pp. 65-8 (1995) Abstract	
	C26	Tenover, J., et al., "Serum Bioactive and Immunoreactive Follicle-Stimulating Hormone Levels and the Response to Clomiphene in Healthy Young and Elderly Men," Journal Clinical Endocrinol. And Metab., Vol. 64, No. 6, pp. 1103-1108 (1987)	
G	C27	Tenover, J., et al., "The Effects of Aging in Normal Men on Bioavailable Testosterone and Luteinizing Hormone Secretion: Response to Clomiphene Citrate," Journal Clinical Endocrinol. Metab., Vol. 65, No. 6, pp. 1118-1126 (1987)	
	C28	U.S. Pharmacopeia, United States Pharmacopeia, 26 th Ed., pp. 484-485 (2003)	

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